

## REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on July 28, 2005. Claims 1, 3-11 and 17-18 are pending in this application. Claim 2 was previously canceled. Claims 12-16 were previously withdrawn. In the Office Action, the specification is objected to, Claims 1, 3-7, 11 and 17 are rejected under 35 U.S.C. §101, Claims 1 and 3-11 are rejected under 35 U.S.C. §112, first paragraph, Claims 8-10 and 18 are rejected under 35 U.S.C. §112, second paragraph, Claims 1, 3-7, 11 and 17 are rejected under 35 U.S.C. §102 and Claim 3 is rejected under 35 U.S.C. §103. In response, the specification and Claims 1, 8, 17 and 18 have been amended, and Claim 19 has been added. This amendment does not add new matter. In view of the amendment and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, the specification is objected to. In response, Applicants have amended the specification to address the informalities cited by the Patent Office. Accordingly, Applicants respectfully request that the objections to the specification be withdrawn.

In the Office Action, Claims 1, 3-7, 11 and 17 are rejected under 35 U.S.C. §101. In response, Applicants have amended independent Claims 1, 17 and 18 to recite, in part, osteoprotegerin isolated from human or bovine milk or colostrums. Further, Applicants have added Claim 19 that recites, in part, osteoprotegerin obtained from recombination methods in cells yielding a glycosylation pattern as found in the milk-OPG. The amendments are fully supported in the specification, for example, at page 7, line 29 to page 8, line 14. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §101 be withdrawn.

In the Office Action, Claims 1 and 3-11 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Patent Office alleges that there is a lack of description for osteoprotegerin that includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 80, 130 and 200 kDa. Applicants respectfully submit that there is sufficient support in the specification that one skilled having ordinary skill in the art would reasonably conclude that the Applicants had possession of the claimed invention. For example, the specification states that the OPG of the present invention may be obtained from a milk source, derived from a mammal, in particular from human or bovine milk or colostrum. Human milk OPG has an amino acid

sequence of 380 aa and exhibits a molecular weight of approximately 80, 130 and 200 kda when compared to protein markers which were used as molecular weight standards (e.g. BioRad). Applicants provide further details regarding the detected bands in the Western Blot Analysis example. See, specification, page 12, lines 10-13. Because these claimed elements are sufficiently described in the specification, one having ordinary skill in the art would understand that Applicants had possession of the claimed subject matter even without additional figures. Based on at least these noted reasons, Applicants believe that Claims 1 and 3-11 fully comply with 35 U.S.C. §112, first paragraph.

In the Office Action, Claims 8-10 and 18 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In response, Claims 8 and 18 have been amended to include a step of adding the osteoprotegerin to a food material, an enteral composition or a pharmaceutical composition. The amendment is fully supported in the specification, for example, at page 3, lines 11-30. Based on at least these noted reasons, Applicants believe that Claims 8-10 and 18 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §112 be withdrawn.

In the Office Action, Claims 1, 4-7, 11 and 17 are rejected under 35 U.S.C. §102(b) as anticipated by Clinical and Experimental Immunology, 104, 543-546 (June 1996) to D'Ostilio et al. ("*D'Ostilio*") as evidenced by US 2004/0137074. Applicants respectfully disagree with and traverse this rejection for at least the reasons set forth below.

The instant claims recite, in part, osteoprotegerin isolated from human or bovine milk or colostrum or obtained from recombination methods, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 80, 130 and 200 kDa. Contrary to the present claims, *D'Ostilio* fails to disclose or suggest osteoprotegerin isolated from human or bovine milk or colostrum or obtained from recombination methods. In fact, *D'Ostilio* fails to even mention osteoprotegerin. Instead, *D'Ostilio* is directed to 90K (Mac-2 BP) found in human breast milk.

For the reasons discussed above, Applicants respectfully submit that Claims 1 and 17 and Claims 4-7 and 11 that depend from Claim 1 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 4-7, 11 and 17 under 35 U.S.C. §102 be withdrawn.

Claim 3 is rejected under 35 U.S.C. §102(b) as being anticipated by *D'Ostilio*, or alternatively under 35 U.S.C. §103(a) as obvious over *D'Ostilio* and WO 99/53942 to Simonet et al. ("*Simonet*"). Applicants respectfully submit that the patentability of Claim 1 renders moot the anticipation and obviousness rejections of Claim 3 that depends from Claim 1. In this regard, the cited art fails to teach or suggest the elements of Claim 3 in combination with the novel elements of Claim 1.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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